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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|----------------------|------------------|
| 09/804,690 | 03/12/2001 | Stanley N. Cohen | S93-160/CIP/DIV2/CON | 1876 |

7590 01/02/2004
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EXAMINER

YU, MISOOK

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/804,690 | COHEN ET AL. | |
| | Examiner | Art Unit | |
| | MISOOK YU, Ph.D. | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-49 is/are pending in the application.
- 4a) Of the above claim(s) 28-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims 28-47 drawn to an invention nonelected with traverse in Paper No. 15. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 28-49 are withdrawn from further consideration for reason of record. Claims 23-49 are pending and claims 23-27 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The objection of the specification is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112

The rejection of claims 23-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** because the Office interprets the amino acid sequence disclosed in Maucuer et al is an epitope of the instantly claimed antibody since applicant does not say on the record said amino acid sequence is not part of an epitope instantly claimed antibody binds to. See 103 rejection below for further elaboration on this point.

Claims 23-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the two species disclosed in the specification is similar and other mammalian species would have similar sequences, therefore antibodies prepared would be paradigmatic for the other mammalian species, genes are highly conserved among species, there is a large number of patents where the same exemplification has permitted claiming the same genus. These arguments have been fully considered but found unpersuasive because the specification does not describe what constitutes a wild-type TSG 101 protein with any associated function.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is two mammalian species. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the

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'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, given that the specification has only described SEQ ID NO: 2 and 4. Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO: 2 and 4, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is separable from its enablement provision (see page 1115).

This rejection affects all dependent claims.

Claim Rejections - 35 USC § 103

Claims 23-26 remain rejected for reason of record under 35 U.S.C. 103(a) as being unpatentable over Maucuer et al (April 1995, Proc. Natl. Acad. Sci. USA, vol. 92, pages 3100-3104) in view of Campbell, A. (1986, Monoclonal antibody technology, Elsevier Science Publishers B.V., Chapter 1 only, pages 1-32) and Levinson et al (1994, Medical Microbiology & Immunology, 3rd edition pages 292 and 293 only).

The claims are interpreted as drawn to antibody capable of binding to instant SEQ ID NO:2 (mouse) and/or SEQ ID NO:4 (human).

Applicant argues that Maucuer never had the polypeptide, but the protein sequence in Maucuer is deduced sequence. The argument has been fully considered but found unpersuasive because Maucuer et al teach 82 amino acid sequence CC2

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protein, which is identical to amino acid #231 to 312 of instant SEQ ID NO:4 except two amino acids at position #237 and #275. Campbell, A. teaches that making monoclonal and polyclonal antibodies is a routine matter (see Table 1.1 at page 5) once the amino acid sequence is known and one of ordinary skill in the art is motivated to make antibody for various reasons (see the last paragraph of page 29). Levinson et al teach that 5 amino acids could elicit and react with antibody. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make an antibody and/or monoclonal antibody using an epitope from the primary reference (for example amino acids #240-265 of CC2 protein, note the attached sequence alignment) that are capable of specifically binding to the instant SEQ ID NO:2 and/or SEQ ID NO:4.

Claims 26 and 27 remain rejected for reason of record under 35 U.S.C. 103(a) as being unpatentable over Maucuer et al in view of Campbell, A. and Levinson et al as applied to claim 23 above, and further in view of Harlow et al (1988, Antibodies, Contents at page iii-ix, 175, 321-3 only).

Claim 26 is drawn to a labeled antibody to TSG101 and claim 27 is drawn to a TSG101 antibody attached to a solid support. Harlow et al teach that labeling an antibody and attaching an antibody to a solid support is a routine matter.

Applicant does not argue.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Misook Yu
December 27, 2003

